Subject: Comments on Nominations to NTP for Toxicology Studies
Date: Monday, October 18, 2004 3:47 PM
From: Judy Stadler <JUDY.STADLER@usa.dupont.com>
To: "Masten, Scott (NIH/NIEHS)" <masten@niehs.nih.gov>

<<NTP Letter telomer studies 10_18.doc>>

DuPont is submitting these comments on the nominations of perfluorinated compounds for NTP Toxicology studies. A signed copy of the attached letter will be sent by US Mail.

DuPont Haskell Laboratory has been engaged in extensive research with the subject compounds and would like to participate in discussions with you regarding studies you may decide to undertake. Please direct comments and inquiries to Robert W. Rickard, Science Director, DuPont Haskell Laboratory for Health and Environmental Sciences. Pertinent contact information is included in the letter.

(See attached file: NTP Letter telomer studies 10_18.doc)

October 18, 2004

Scott A. Masten, Ph.D.
Office of Chemical Nomination and Selection
Environmental Toxicology Program
National Institute of Environmental Health Sciences
P.O. Box 12233, MD A3-07
111 T.W. Alexander Drive, Room A326
Research Triangle Park, USA 27709

Dear Dr. Masten:

This letter is being written to comment on the NTP testing program announced in the August 20 Federal Register notice (60 Fed Reg. 51, 691). We would like to inform you of the toxicology data and studies that are in progress or have been completed at DuPont Haskell Laboratory in the categories of data you are seeking on the perfluorinated compounds, as outlined in the letter addressed to you from Charles Auer dated August 7, 2003. These studies are part of an extensive program of toxicology testing on the fluorotelomers sponsored by the DuPont Company and, where indicated, the Telomers Research Program, an inter-industry consortium of which DuPont is a member. We have already generated some of the data of interest or have studies presently in progress that address the categories of data that have been described.

1. Fluorocarboxylic acids

We have conducted a series of screening studies in which rats were dosed with either the C6, C8, or C10 carboxylic acid for ten days and then held for an additional 84 days. Periodic blood samples, fat, and liver samples were taken and analyzed for the presence of total fluorine.

2. Fluorotelomeric alcohols

a. Telomer alcohol 8+2

The Telomer Research Program has completed a 90-day subchronic toxicity study and developmental toxicity study in rats with this purified alcohol. DuPont has in progress an extensive pharmacokinetics study program that includes comparative *in vitro* metabolism, ADME following oral dosing*, in vitro* and *in vivo* dermal kinetics, biliary elimination, and plasma kinetics.

b. Telomer B alcohol production mixture

We have completed a series of studies with a telomer B alcohol mixture that contains approximately equal thirds of the 6+2, 8+2 and 10+2 alcohols. The studies include a 90-day subchronic study, developmental toxicity study, and a one-generation reproduction study.

c. Telomer alcohol 10+2

We have conducted a screening study in which rats were dosed with the 10+2 alcohol for 10 days and held for an additional 84 days, in a protocol similar to that described for fluorocarboxylic acids.

Manuscripts on the work with the Telomer B alcohol production material have been submitted for publication in *Drug and Chemical Toxicology* and are scheduled to appear early in 2005. Manuscripts of the 90-day subchronic study, the developmental toxicity study and the pharmacokinetics studies with the 8+2 alcohol are being prepared for submission in late 2004 or early 2005. Should you decide to proceed with any of the studies you have listed on the perfluorinated compounds referenced above, we will be happy to meet with you to discuss study design and share details of the completed studies with you.

Sincerely yours,

Robert W. Rickard, Ph.D.
Science Director
DuPont Haskell Laboratory

Telephone No: (302) 366-6318
Fax No: (302) 451-4828
e-mail: robert.w.rickard@usa.dupont.com